

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

March 31, 2015

EPA Reg#: 67603-RE		DP Barcode: 424256	
		Submission #: 960115	E-Submission: 6753
Product name: Sanitizer #1		Registrant: Sherwin-Williams Diversified Brands	
Reviewer's name: Juan F. Negrón		AD/PSB/CTT- Product Chemistry Reviewer	
Agency due date: 04/27/15		PSB received date: 12/09/14	
CTT received date: 12/09/14		Science received date: 12/09/14	
Formulation type: EUP		Pesticide classification: Disinfectant, sanitizer, bactericide	
Integrated system: <input type="checkbox"/>	Non-integrated system: <input checked="" type="checkbox"/>	Food use: <input type="checkbox"/>	Non food use: <input checked="" type="checkbox"/>
Action Code: A540		Date Completed: 03/29/2015	
PC Code(s)	CAS #(s)	Active Ingredient Names	% wt (label)
069105	68424-85-1	n-Alkyl (50%C ₁₄ , 40%C ₁₂ , 10%C ₁₆) dimethyl benzyl ammonium chloride	0.52
Molecule structure (optional):			
MRID:		Guideline: 830 Groups A & B	
Comments:			
Approver: Karen P. Hicks		Approved date: 03/31/2015	

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Antimicrobials Division (AD)

March 31, 2015

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 67603-RE
Product Name: Sanitizer #1
DP Barcode: 424256

From: Juan F. Negrón, Chemist 
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader 
Product Science Branch
Antimicrobials Division (7510P)

To: Velma Noble / John C Cowden
PM Team 31

APPLICANT: Sherwin-Williams Diversified Brands
Action code: A540
Due date: 04/27/2015

Product Formulation
Active Ingredient from label:

	% by wt.
n-Alkyl (50%C ₁₄ , 40%C ₁₂ , 10%C ₁₆)	
dimethyl benzyl ammonium chloride	0.52

BACKGROUND:

On behalf of the registrant, Sherwin-Williams Diversified Brands, the consultant, Technology Sciences Group, Inc. (TSG), is submitting an application for a new end-use product registration for "Sanitizer #1" as a non-integrated system. The product intends to make efficacy claims. This product is for interior use on ceilings, walls, doors, and trims in nursing homes, patient care centers, doctor and dentist offices, residencies, and non-critical areas of hospitals. The product is a latex paint for use in controlling human pathogens on painted surfaces. The paint will be sold only through stores owned and operated by The Sherwin-Williams Company. The Product Chemistry Reviewer has reviewed the following documents:

- Confidential Statements of Formula (CSFs), dated 10/30/2014, for the basic and alternate (#1) formulations.
- A draft label, dated 10/30/2014.
- A transmittal document, dated 10/30/2014.
- A letter, dated 10/30/2014 MRID # 49420300.
- Data matrix, dated 10/30/2014.
- Formulators' Exemption Statement, dated 10/30/2014.
- Application for a pesticide registration, dated 10/30/2014.
- Certification with respect to citation of data, dated 10/30/2014.
- A study titled "Product Chemistry of Sanitizer #1 - Group A" dated 07/17/2014 MRID # 49420301.
- A study titled "Product Chemistry of Sanitizer #1 - Group B" dated 07/17/2014 MRID # 49420302.

FINDINGS:

1. The CSFs, dated 10/30/2014, for the basic and alternate (#1) formulations are revised.
2. The CSFs and the label have the same nominal concentration for the active ingredient (AI).
3. All components meet the EPA Standard Certified Limits.
4. The product contains trade names that are not in the Agency inert ingredients database.
5. None of the [REDACTED] are in the Agency inert ingredient database from the CSF alternate #1 formulation.
6. The registrant has submitted to the Agency the 830 Groups (A & B) guidelines which have met the requirements for registration, except for the one-year Storage Stability and Corrosion Characteristics studies. These studies are ongoing and will be submitted upon completion.

CONCLUSIONS:

The CSFs, dated 10/30/2014, for the basic and alternate (#1) formulations are not acceptable. The CSFs shows trade names and [REDACTED] that are not in the Agency database. The requirements of the product chemical package have been met, except for the one-year Storage Stability and Corrosion Characteristics studies. These studies are ongoing and will be submitted upon completion.

RECOMMENDATIONS:

1. The registrant must contact the supplier for those trade names and [REDACTED] that are not in the Agency inert ingredient database. The supplier must provide to the Agency the full compositional data.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [x]
- Are all TGAIs used registered? Yes [x] No []
- Integrated formulation system []
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food:

Yes [x] No []

c. Physical state of product:

liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredients

	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
n-Alkyl (50%C ₁₄ , 40%C ₁₂ , 10%C ₁₆)			
dimethyl benzyl ammonium chloride	0.52	0.572	0.468

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☐ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL

Yes ☐ No ☐

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity	A	49420301
830.1600 Description of Materials	A	49420301
830.1620 Production Process	NR The end-use product is a non-integrated system.	49420301
830.1650 Formulation Process	A	49420301
830.1670 Formation of Impurities	NR The end-use product is a non-integrated system.	49420301
830.1700 Preliminary Analysis	NR The end-use product is a non-integrated system.	49420301
830.1750 Certified Limits	A	49420301
830.1800 Enforcement Analytical Method	A See EPA Reg# 67071-68.	49420301
830.1900 Submittal of Samples	Available upon request.	49420301

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable; NR= not required; G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NR	[Not required for end-use products.] However, the registrant has indicated that the color is colorless.	4942030 2
830.6303 Physical State	A	liquid	4942030 2
830.6304 Odor	NR	[Not required for end-use products.]	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	[Not required for end-use products.]	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Sanitizer #1 was nonreactive to water, iron, kerosene, 10% mono-ammonium phosphate and 10% potassium permanganate.	4942030 2
830.6315 Flammability/ Flame Extension	A	Sanitizer #1 has no flash point, after being boiled at 100°C. From its chemical composition, neither the [REDACTED] nor the [REDACTED] of Sanitizer #1 have any capacity to cause or support combustion.	4942030 2
830.6316 Explodability	A	This product is not potentially explosive.	4942030 2
830.6317 Storage Stability	G	The registrant will submit the study upon completion.	4942030 2
830.6319 Miscibility	A	Sanitizer #1 is miscible with water in all proportions	4942030 2
830.6320 Corrosion Characteristics	G	The registrant will submit the study upon completion.	4942030 2
830.6321 Dielectric Breakdown Voltage	A	Product is not intended for used around electrical equipment.	4942030 2
830.7000 pH	A	7.59 @ 25°C a 1% suspension of the product in water.	4942030 2
830.7050 UV/Visible Absorption	NR	[Not required for end-use products.]	
830.7100 Viscosity	A	2165.136 cSt @ 20°C & 892.102 cSt @ 40°C	4942030 2
830.7200 Melting Point/Melting Range	NR	[Not required for end-use products.]	
830.7220 Boiling Point/Boiling Range	NR	[Not required for end-use products.]	
830.7300 Density/Relative Density/Bulk Density	A	1.347 g/ml @ 25°C.	4942030 2
830.7370 Dissociation Constants in Water	NR	[Not required for end-use products.]	
830.7520 Particle Size	NR	[Not required for end-use products.]	
830.7550/830.7560/830.7570 Partition Coefficient	NR	[Not required for end-use products.]	
830.7840/830.7860 Water Solubility	NR	[Not required for end-use products.]	
830.7950 Vapor Pressure	NR	[Not required for end-use products.]	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required; G=data gap.

